

***Election Requirement Based On Alleged Distinctness***

In the present Office Action, the Examiner continued to rely on a prior election requirement under 35 U.S.C. §121 that the Examiner originally stated in the Office Action that was mailed on March 31, 2000. The Examiner's prior election requirement placed claims "1-14, 19-24, drawn to Methods of Feed Administration, classified in Class 424, Subclass 438" in Group I, placed claims "15-18, drawn to Feed Production, classified in Class 426, Subclass 54 in Group II, and placed claims "25-27, drawn to Feed, classified in Class 14, Subclass 738 in Group III.

In response to this Election requirement and the Examiner's arguments in support of this Election Requirement, Applicant challenged the Examiner's basis for alleging distinctness between the invention defined by the claims that were placed in Groups I and II and also challenged the Examiner's basis for alleging distinctness between the invention defined by the claims that were placed in Groups II and III. In response to these prior arguments challenging the alleged distinctness, the Examiner, in the present Office Action, merely stated:

The traversal is on the ground(s) that Applicant argues in the Groups (sic) are not distinct and examiner is erroneous in characterizing the product as bait. This is not found persuasive because examiner finds the classification, products and processes warrant separate considerations, and would result in separate, patentable, (sic) after multiple, burdensome search. The requirement is still deemed proper and is therefore made FINAL.

This response of the Examiner does not address or rebut Applicant's challenges of the Examiner's distinctness arguments that Applicant provided in response to the prior Office Action. Therefore, this argument, because it completely fails to address the distinctness requirement, as challenged by Applicant, does not in any way establish that the alleged Group I and Group II inventions are distinct or that the alleged Group II and Group III inventions are distinct. The Manual of Patent Examining Procedure ("M.P.E.P.") 97<sup>th</sup> Edition, July 1998), at §803 that is entitled, Restriction - When Proper, states:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent

(MPEP § 806.04 - § 806.04 (i)) or distinct MPEP § 806.05 - § 806.05 (i)).

(Emphasis added). Here, the Examiner relies upon an allegation that distinct inventions are contained in the application. However, Applicant has challenged this allegation about distinctness, and the Examiner has not yet supplied an appropriate response that supports the Examiner's continued distinctness allegations.

Consequently, the Examiner's restriction between the invention of the above-identified application that the Examiner has placed in Groups I, II, and III is improper and should be withdrawn. Therefore, Applicant continues to traverse the Examiner's election requirement between the invention of the above-identified application, as defined in the claims the Examiner has placed in Groups I, II, and III and request reconsideration and withdrawal of this election requirement.

### ***Species Election Requirement***

In the Office Action, the Examiner continues to allege that a species election requirement of the invention, as defined in the claims of the above-identified application is proper. As indicated in Applicant's prior Amendment that was filed in response to the Office Action dated March 31, 2000, Applicant has elected the oral administration species to satisfy the Examiner's species election requirement. Applicant further noted in the Amendment (Paper No. 7) that claims 1-4, 8-11 and 13-14 read on the elected species. Nevertheless, Applicant continues to traverse the Examiner's designation of "surgical" and "infusion" as distinct species.

According to the Examiner:

As to the species requirement this also is maintained, because as claimed, infusion does not have to be as presented in applicants arguments it can (sic) be done via take through the esophageal groove (sic).

The issue raised by the Examiner is whether "surgical" administration and "infusion" administration are distinct species. As pointed out by Applicant in response to the prior Office Action:

The details provided at page 9, line 21, through page 10, line 23, of the above-identified application explain how a ruminant may be surgically fitted with an abomasol infusion tube 22, such as the fistula that is defined in claims 6 and 22. In accordance with the specification of the above-identification, abomasol infusion in accordance with the present invention occurs after first surgically fitting the ruminant with the abomasol infusion tube or fistula. Thus, the Examiner's comments about "surgical, infusion," do not demonstrate that these are separate and distinct "species of administration." Instead, these alleged separate and distinct "species of administration" work in conjunction with each other to achieve the claimed abomasol infusion.

The Examiner alleges that infusion may occur through the "esophageal groove." The Examiner provided no basis or literature citation in support of this bare allegation.

Furthermore, the Examiner is reminded that the claims are to be read in light of the specification. The specification, as indicated above in the recited comments, describe infusion in relation to surgically fitting an abomasol infusion tube or fistula for subsequent infusion. Here, the only evidence we have about infusion is that it is related to surgical fitting of an abomasol infusion tube and a fistula. We have no evidence other than the Examiner's bare allegation that esophageal intake (apparently through oral feeding) pertains to infusion. If the Examiner has any evidence in support of this alleged "esophageal infusion" allegation, the Examiner is requested to share this information with the Applicant.

Further evidence that the Examiner's alleged esophageal infusion approach is erroneous resides in the language of claims that are defined in terms of infusion. Specifically, claims 7 and 23 are the only current claims reciting "infusing." Claims 7 and 23 read as follows:

7. *The method of claim 5 wherein placing the feed directly into the abomasum of the ruminant comprises infusing the feed into the abomasum of the ruminant without passing the feed through any other stomach portions of the ruminant.*

23. *The method of claim 19 wherein supplying the feed directly into the abomasum of the ruminant comprises infusing the feed into*

*the abomasum of the ruminant without passing the feed through any other stomach portions of the ruminant.*

Thus, the two claims that are defined in terms of "infusing" further specify: "without passing the feed through any other stomach portions of the ruminant." Consequently, it is a strain to the imagination to see how claims that are presently defined in terms of "infusing" in the above-identified application would relate to esophageal feeding.

Consequently, based upon this brief explanation, Applicant respectfully requests that the Examiner reconsider and revise the Examiner's definition of "species of administration" and that the Examiner reconsider and withdraw the species election requirement as between the alleged "surgical" and "infusion" species of administration.

***Claims Rejection Under 35 U.S.C. §102(b)***

In the Office Action, the Examiner rejected claims 1-4, 8-11, 13 and 14 under 35 U.S.C. §102(b) as allegedly "being anticipated by" U.S. Patent No. 4,127,676 to Merensalmi (subsequently referred to as the "Merensalmi" patent). In support of this rejection, the Examiner stated:

"Sugar alcohols are supplied orally to milking cows, enhancing milk production (col. 1, lines 5-9) (col. 2, line 14- line 48) and is protected from breakdown in the rumen (col. 3, lines 30-33), to effectively increase blood sugar (Example 3).

Despite the Examiner's comments, the Merensalmi patent does not disclose each and every feature defined in any of claims 1-4, 8-11, or 13-14 and consequently does not anticipate any of claims 1-4, 8-11 or 13-14.

Independent claims 1 and 10 read as follows:

1. *A method of enhancing milk component production in a ruminant, the method comprising:  
providing a feed that comprises a sugar alcohol; and  
supplying the sugar alcohol to the abomasum of the ruminant.*

10. *A method of feeding a ruminant, the method comprising:  
providing a feed that comprises a sugar alcohol; and  
supplying the sugar alcohol to the abomasum of the  
ruminant, the sugar alcohol effective to  
enhance milk component production by the  
ruminant.*

Thus, claims 1 and 10 require enhancing milk component production by supplying a sugar alcohol to the abomasum of the ruminant.

The Merensalmi patent generally discloses a fodder additive for cows that may increase milk production of cows. However, the Merensalmi patent does not disclose anything about the fodder additive enhancing milk **component** concentrations in produced milk. In fact, Applicant directs the Examiner's attention to Column 3, line 64, to Column 4, line 2, of the Merensalmi patent where a net **decrease** in the fat percentage in milk produced by test animals is observed upon start of a sugar alcohol feeding regimen. Additionally, while the Merensalmi patent does disclose an increase in blood sugar levels during test feeding of a test animal, this increase is merely a recovery to levels present at the onset of the test feeding regimen prior to introduction of the sugar alcohol and no corresponding enhancement in milk component concentrations is disclosed. Furthermore, as stated above, this recovery of blood sugar levels is not disclosed to have increased milk component concentrations in produced milk. Instead, the Merensalmi patent discloses only a decrease in fat concentrations in produced milk in reaction to the blood sugar level recovery.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 1 and 10. Consequently, the Merensalmi patent does not anticipate either claim 1 or claim 10 of the above-identified application.

Next, claims 2 and 11 read as follows:

2. *The method of claim 1 wherein supplying the sugar alcohol  
to the abomasum of the ruminant comprises:  
protecting the sugar alcohol from significant  
alteration in the rumen of the ruminant; and  
orally feeding the feed to the ruminant.*

11. *The method of claim 10 wherein supplying the sugar alcohol to the abomasum of the ruminant comprises:  
protecting the sugar alcohol from significant  
alteration in the rumen of the ruminant; and  
orally feeding the feed to the ruminant.*

Therefore, claims 2 and 11 further specify that the sugar alcohol is ruminally-protected from significant alteration in the rumen of the ruminant. The Examiner relies on Column 3, lines 30-33, of the Merensalmi for support of the Examiner's allegation that sugar alcohols of the Merensalmi patent are allegedly ruminally-protected from breakdown in the rumen. However, column 3, lines 30-33, of the Merensalmi do not support the Examiner's allegation that the sugar alcohol mixture of the Merensalmi patent is ruminally-protected. Indeed, there is no teaching, suggestion, or disclosure in the Merensalmi patent whatsoever about any rumen protection of sugar alcohols.

Additionally, though the Merensalmi patent alleges that sugar alcohols may pass through the rumen prior to any essential degradation of the sugar alcohols in the rumen, this allegation is based on *in vitro* test results of exposing sugar alcohols to rumen fluid and not any *in vivo* results pertaining to actual sugar alcohol passage through the rumen of a ruminant. Consequently, this detail of the Merensalmi patent does not teach or disclose anything about sugar alcohol passage through the rumen of a ruminant or about protection of sugar alcohol "from significant alteration," as required by claims 2 and 11. Furthermore, Applicant notes that the *in vitro* testing that is disclosed in the Merensalmi patent is typically not used as a substitute for *in vivo* testing due to extraneous factors that are introduced during *in vivo* testing that are not present under the controlled conditions of *in vitro* testing.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 2 and 11. Consequently, the Merensalmi patent does not anticipate either claim 2 or claim 11 of the above-identified application.

Claims 8 and 14 read as follows:

8. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight*

*percent of total solids, or any combination of these in milk produced by the ruminant.*

14. *The method of claim 10 wherein the sugar alcohol that is supplied to the abomasum of the ruminant is effective to enhance the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight percent of total solids, or any combination of these in milk produced by the ruminant.*

Claims 8 and 14 further define that enhancing milk component production in accordance with the present invention includes enhancing the weight percent of true protein, fat, lactose, and/or total solids in milk that is produced by the ruminant.

The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of true protein, fat, lactose, and/or total solids occurring in the milk produced by the test animals. Additionally, Applicant directs the Examiner's attention to column 3, lines 64-68, that disclose a *decrease* in the fat percentage in milk produced by the test animals of the Merensalmi patent.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 8 and 14. Consequently, the Merensalmi patent does not anticipate either claim 8 or claim 14 of the above-identified application.

Next, claims 3 and 4 read as follows:

3. *The method of claim 2, the method further comprising protecting the sugar alcohol from substantial alteration in the rumen of the ruminant.*

4. *The method of claim 2, the method further comprising protecting the sugar alcohol from any alteration in the rumen of the ruminant.*

Thus, claims 3 and 4 each pertain to protection of the sugar alcohol from alteration in the rumen of the ruminant. Claim 3 requires protection from "substantial alteration in the rumen of the ruminant", while claim 4 requires protection from "any alteration in the rumen of the ruminant."

The Merensalmi patent does not teach or disclose anything about protecting sugar alcohol from alteration in the rumen of the ruminant. Indeed, nothing is provided in the Merensalmi patent about any steps taken to protect the sugar alcohol from such alteration. Instead, the Merensalmi patent, at column 2, line 60, through column 3, line 29, merely presents testing information about the effect of rumen fluid on various sugar alcohols. Furthermore, this testing does teach or disclose anything about taking protective steps to alter rumen fluid degradation of the sugar alcohols.

Furthermore, the Merensalmi testing only concerns *in vitro* testing in rumen fluid, and does not teach or disclose anything about the effect of passage of sugar alcohols through the rumen of a ruminant, since the Merensalmi patent merely concerns the *in vitro* testing in rumen fluid. As previously explained, the *in vitro* testing that is disclosed in the Merensalmi patent is typically not used as a substitute for *in vivo* testing due to extraneous factors that are introduced during *in vivo* testing that are not present under the controlled conditions of *in vitro* testing, such as the *in vitro* testing that is presented in the Merensalmi patent. Furthermore, with respect to the requirement of claim 4 that the sugar alcohol be protected from "any alteration" in the rumen of the ruminant, Applicant notes that the *in vitro* testing results disclosed in the Merensalmi patent (at column 2, line 60, through column 3, line 29) **do** disclose degradation of sugar alcohol in the rumen fluid during the *in vitro* testing.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each and every feature that is required by either claim 3 or claim 4. Consequently, the Merensalmi patent does not anticipate either claim 3 or claim 4.

Claims 1-4, 8, 10-11, and 14 are each believed allowable. Claim 9 is also believed allowable, since claim 9 depends from allowable claim 1. Also claim 13 is believed allowable since claim 13 depends from allowable claim 10. Furthermore, claims 2-4, 8, 11 and 14 are believed allowable for an additional reason, since claims 2-4 and 8 each depend from allowable claim 1 and since claims 11 and 14 each depend from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-4, 8-11, and 13-14



under 35 U.S.C. §102 based upon the Merensalmi patent and that claims 1-4, 8-11, and 13-14 be allowed.

***Claim Rejections Under 35 U.S.C. §103(a)***

In the Office Action, the Examiner rejected claims 1-4, 8-11, and 13-14 under 35 U.S.C. §103(a) as allegedly “being unpatentable over” the Merensalmi patent in view of U.S. Patent No. 3,959,493 to Baalsrud (subsequently referred to as the “Baalsrud patent”). In support of this rejection, the Examiner stated:

Merensalmi (above/provides sugar alcohols to the abomasum, effectively, protected while traversing the rumen, but not in a typical rumen by pass format. But, it is also noted that the alcohols replace glycerol, propionate and propionic acid (col. 1, bottom).

Baalsrud provides an example of Rumenal by pass, for delivery of propionic (sic) and (col. 3) to enhance milk production.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize as by pass composition, (sic) to use one of Merensalmi, modified with Baalsrud to provide acceptable application.

Baalsrud teaches one having ordinary skill in the art would be motivated to perform this modification in order to increase amount of desired component to reach abomasum.

Despite the Examiner’s comments, the Merensalmi patent and the Baalsrud patents, either separately or in combination, do not teach, suggest, disclose, or render obvious the invention of the above-identified application, as defined in claims 1-4, 8-11, and 13-14.

Applicant first considers the Examiner’s statement about the Baalsrud patent allegedly providing an example of ruminal bypass “for delivery of propionic . . . to enhance milk production.” This comment of the Examiner is not understood, since the only comment in column 3 that may relate to this allegation appears at column 3, lines 45-50 of the Baalsrud patent. Here, the Baalsrud patent merely talks about glucose derivation from propionate that originates upon decomposition of

carbohydrates in the rumen. Thus, it appears that the Examiner's comments about rumen bypass protection of "propionic" is off the mark and bears no real relation to the disclosure in the Baalsrud patent. Instead, these comments in the Baalsrud patent that are referenced by the Examiner appear to merely provide some background information about carbohydrate decomposition in the rumen.

As noted above, claims 1 and 10 read as follows:

1. *A method of enhancing milk component production in a ruminant, the method comprising:  
providing a feed that comprises a sugar alcohol; and  
supplying the sugar alcohol to the abomasum of the ruminant.*
10. *A method of feeding a ruminant, the method comprising:  
providing a feed that comprises a sugar alcohol; and  
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol effective to enhance milk component production by the ruminant.*

Thus, claims 1 and 10 each define a "method of enhancing milk component production in a ruminant."

As noted above, the Merensalmi patent does not teach disclose anything about enhancement of milk component production. The Examiner seeks to remedy this problem by relying upon the Baalsrud patent. However, the Baalsrud patent likewise does not disclose anything about milk **component** production enhancement, but instead generally concerns enhancement of milk production by rendering carbohydrates rumen inert. Consequently, even when the disclosures of the Baalsrud patent and the Merensalmi patent are considered, either separately or in combination, the net result is no disclosure, no teaching, and no suggestion about any milk **component** production enhancement.

The Merensalmi and Baalsrud patents, either separately or in combination, do not teach, suggest, or disclose the invention of the above-identified application, as defined in claims 1 and 10. Consequently, claims 1 and 10 are believed allowable despite the Examiner's rejection under §103 based upon the Merensalmi and Baalsrud patents.

Next, claims 2 and 11 read as follows:

2. *The method of claim 1 wherein supplying the sugar alcohol to the abomasum of the ruminant comprises:*

*protecting the sugar alcohol from significant alteration in the rumen of the ruminant; and orally feeding the feed to the ruminant.*

11. *The method of claim 10 wherein supplying the sugar alcohol to the abomasum of the ruminant comprises:*

*protecting the sugar alcohol from significant alteration in the rumen of the ruminant; and orally feeding the feed to the ruminant.*

Thus, claims 2 and 11 each require sugar alcohol protection "from significant alteration in the rumen of the ruminant." As discussed above, the Merensalmi patent does not disclose or otherwise teach or suggest anything about any such sugar alcohol protection. Consequently, the Examiner relies upon the Baalsrud patent to correct this deficiency. However, the Baalsrud patent does not address sugar alcohols. Instead, the Baalsrud patent generally talks about the possibility of ruminally protecting carbohydrates. However, the Baalsrud patent does not address rumen protection of carbohydrates in relation to milk component production enhancement. Instead, the Baalsrud patent only concerns overall milk production enhancement. Thus, taken together, the Baalsrud and Merensalmi patents do not teach, suggest, or disclose anything about sugar alcohol protection "from significant alteration in the rumen of the ruminant", in relation to milk component production enhancement.

The Merensalmi and Baalsrud patents, either separately or in combination, do not teach, suggest, or disclose the invention of the above-identified application, as defined in claims 2 and 11. Consequently, claims 2 and 11 are believed allowable despite the Examiner's rejection under §103 based upon the Merensalmi and Baalsrud patents.

Next, claims 8 and 14 read as follows:

8. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight*

*percent of total solids, or any combination of these in milk produced by the ruminant.*

14. *The method of claim 10 wherein the sugar alcohol that is supplied to the abomasum of the ruminant is effective to enhance the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight percent of total solids, or any combination of these in milk produced by the ruminant.*

Thus, claims 8 and 14 specify supply of sugar alcohol to the abomasol of the ruminant that is effective to enhance the weight percent of true protein, fat, lactose, total solids, or “any combination of these” in milk that is produced by the ruminant.

As discussed above, there is nothing pertaining to enhancement of any of these milk **components** in the Merensalmi patent. Therefore, the Examiner attempts to remedy this deficiency by relying on the Baalsrud patent. However, as noted above, the Baalsrud patent only concerns overall milk production enhancement, rather than milk **component** enhancement. Consequently, claims 8 and 14 are believed allowable, since the Merensalmi patent and the Baalsrud patent, either separately or in combination, do not teach, suggest, disclose, or render obvious all of the features that defined in claims 8 and 14 of the above-identified application.

Finally, claims 3 and 4 read as follows:

3. *The method of claim 2, the method further comprising protecting the sugar alcohol from substantial alteration in the rumen of the ruminant.*

4. *The method of claim 2, the method further comprising protecting the sugar alcohol from any alteration in the rumen of the ruminant.*

Claims 3 and 4 each concern protection of sugar alcohol from alteration in the rumen of the ruminant. Claim 3 concerns protection from “substantial alteration in the rumen of the ruminant,” whereas claim 4 concerns protection from “any alteration in the rumen of the ruminant.” As explained above, the Merensalmi patent does not teach, suggest, or disclose anything whatsoever about such sugar alcohol protection from alteration in the rumen of the ruminant. Consequently, the Examiner relies upon the Baalsrud patent for providing this protective element to the sugar alcohol.

However, the Baalsrud patent merely concerns making carbohydrates rumen inert and does not address sugar alcohols. Furthermore, there is nothing whatsoever in the Baalsrud patent about protecting sugar alcohols to prevent "substantial alteration" of the sugar alcohols, as required by claim 3. Likewise, there is nothing whatsoever in the Baalsrud patent about protecting the sugar alcohol to prevent "any alteration" of the sugar alcohol, as required by claim 4.

The Merensalmi and Baalsrud patents, either separately or in combination, do not teach, suggest, or disclose the invention of the above-identified application, as defined in claims 3 and 4. Consequently, claims 3 and 4 are believed allowable despite the Examiner's rejection under §103 based upon the Merensalmi and Baalsrud patents.

Claims 1-4, 8, 10-11, and 14 are each believed allowable. Claim 9 is also believed allowable, since claim 9 depends from allowable claim 1. Also claim 13 is believed allowable since claim 13 depends from allowable claim 10. Furthermore, claims 2-4, 8, 11 and 14 are believed allowable for an additional reason, since claims 2-4 and 8 each depend from allowable claim 1 and since claims 11 and 14 each depend from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-4, 8-11, and 13-14 under 35 U.S.C. §103 based upon the Merensalmi patent and the Baalsrud patent and that claims 1-4, 8-11, and 13-14 be allowed.

#### ***Provisional Double-Patenting Rejection***

In the Office Action, the Examiner rejected claims 1-4, 8-11, and 13-14 under a provisional obvious-type double patenting rejection as allegedly "being unpatentable over claim 1-15 of copending Application No. 09/338314." According to the Examiner, "Although the conflicting claims are not identical, they are not patentably distinct from each other because the 338 application encompasses the claimed subject matter.

Due to the provisional nature of this double patenting rejection, Applicant respectfully requests an opportunity to address this provisional rejection after prosecution has progressed in "copending Application No. 09/338314" to a point where this provisional rejection either becomes a non-provisional rejection or the basis for this provisional rejection becomes moot. If the non-

provisional double-patenting rejection becomes a non-provisional double-patenting rejection, Applicant is prepared to take appropriate action to address any such non-provisional double-patenting rejection. These comments are believed to adequately address this provisional double-patenting rejection of the Examiner.

***New Claims Added By Applicant***

Applicant has added new claims 28-37, as indicated above. Support for new claims 28-37 is believed to exist in the above-identified application. Applicant respectfully requests consideration and allowance of new claims 28-37.

**CONCLUSION**

Claims 1-4, 8-11, and 13-14 are each believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-4, 8-11, and 13-14 and that claims 1-4, 8-11, and 13-14 be allowed. New claims 28-37 are believed allowable. Consequently, Applicant respectfully requests that the Examiner consider and allow new claims 28-37. The Examiner is invited to contact Applicant's below-named attorney to discuss any aspect of this application and advance this application to allowance.

Respectfully submitted,

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